

WORKSHOP ON INTUSSUSCEPTION, ROTAVIRUS, AND ORAL VACCINES

September 5–7, 2001

Key Bridge Marriott, Roslyn, Virginia

DRAFT AGENDA 08/03/2001

Convened by the National Vaccine Program Office and the National Vaccine Advisory Committee

Objectives:

1. To provide a forum to examine data obtained since the January 1999 workshop.
2. To identify the burdens of intussusception and rotavirus infection in different populations.
3. To review recent information on the pathogenesis of intussusception.
4. To define the rate of intussusception following receipt of RRV and other vaccines administered by the oral route.
5. To consider means to compare the risks and benefits of candidate rotavirus vaccines.

Organizing Committee:

NVPO: Martin Myers
NCID: Roger Glass
NIP: Ben Schwartz
NIH: George Curlin

FDA: Norman Baylor
NVAC: Pat Fast
HRSA: Vito Caserta

WEDNESDAY, SEPTEMBER 5—DAY 1

8 a.m. Welcome Martin Myers

Session 1. Introduction

Moderator: Pat Fast

8:00–8:10	Introduction	Martin Myers
8:10–8:20	Summary of the First Workshop	Mike Gerber
8:20–8:30	Historical Summary—ACIP	John Modlin
8:30–8:40	Summary of the WHO Workshop	Dixie Snider
8:40–8:50	May 2001 GAVI Recommendations	Joe Bresee
8:50–9:05	U.S. Rotavirus Disease Burden	Roger Glass
9:05–9:20	Disease Burden in India	M.K. Bhan
9:20–9:35	Global Rotavirus Disease Burden	Umesh Parashar
9:35–10:05	Open Discussion	

10:05–10:35 Break

Session 2. Vaccine Prevention of Rotavirus Morbidity and Mortality

Moderator: C.D. Atreya

- 10:35–11:00 Live Oral Vaccines To Prevent Rotavirus Morbidity and Mortality Al Kapikian
- 11:00–12:00 **Round Table Discussion:** Vaccines in Development
Participants: Harry Greenberg, Paul Offit, Richard Ward, Al Kapikian

12:00–1:00 Lunch

Session 3. Intussusception Recognition and Disease Burden

Moderator: David Matson

- 1:00–1:15 Early Detection Kathy Edwards
- 1:15–1:30 Early Detection Harry Greenberg
- 1:30–1:40 Acute Intussusception in Infants and Children Julie Bines
- 1:40–2:05 Bloody Diarrhea as a Possible Signal for Intussusception Bob Chen
- 2:05–2:25 Epidemiology and Disease Burden in the United States Mary Staat
- 2:25–2:45 Epidemiology and Disease Burden in India M.K. Bhan
- 2:45–3:20 Discussion

3:20–3:50 Break

Session 4. Pathogenesis of Intussusception

Moderator: David Bernstein

- 3:50–4:10 Pathology (IAG Study) Wun-Ju Shieh
- 4:10–4:30 Animal Models Margaret Connor
- 4:30–4:50 A Critique of Wild-Type Rotavirus as an Etiology of Intussusception Margaret Rennels
- 4:50–5:20 **Round Table Discussion*:** Strain Differences That May Relate to Differences in Risk of Intussusception
Participants: Paul Offit, Mary Estes, John Patton, T. Nakagomi

5:20 p.m. Adjourn

6:30 p.m. No-Host Social Gathering

THURSDAY, SEPTEMBER 6—DAY 2

Session 5. Rhesus Rotavirus Experience

Moderator: Myron Levin

8:00–8:15	Pre-licensure Clinical Trials and Licensing	Margaret Rennels
8:15–8:30	Initial ACIP and AAP Recommendations	Larry Pickering
8:30–8:45	Vaccine Distribution: Industry Perspective	Peter Paradiso
8:45–9:00	Vaccine Distribution: National Immunization Survey	Ben Schwartz
9:00–9:30	Case Control Study	Trudy Murphy
9:30–10:00	Cohort Study	Piotr Kramerz

10:00–10:30 Break

10:30–11:00	Follow-up of the Cohort Study	Phil Rhodes
11:00–11:30	Capture-Recapture Study	Tom Verstaeten
11:30–12:00	Ecological Studies—New York	Hwa-Gan Chang
12:00–12:30	Ecological Studies	Lone Simonsen

12:30–1:30 Lunch

Session 6. Assessing Attributable Risk

Moderator: Ben Schwartz

1:30–2:00	Assessing Assessments of Point Estimates of Coverage	Susan Ellenberg
2:00–2:30	Assessing Attributable Risks From Data Derived From Different Study Designs	Alec Walker
2:30–2:45	Critique of the Six Studies' Design, Strengths, and Weaknesses	Gene Shapiro
2:45–3:00	Critique of the Six Studies' Design, Strengths, and Weaknesses	James Schlesselman

3:00–3:30 Break

3:30–4:30 **Round Table Discussion*:** What Is the Best Estimate of the
Attributable Risk of Intussusception Following RRV?

Moderator: Alec Walker

Participants: Gene Shapiro, James Schlesselman, John La Montagne,
Walt Orenstein

4:30–5:00 Open Discussion

5 p.m. Adjourn

FRIDAY, SEPTEMBER 7—DAY 3

8 a.m. Reconvene

Session 7. Is Intussusception Associated With Other Oral Vaccines?

Moderator: Mike Levine

8:00–8:20	The Infant Gut: Oral Vaccines (Other Than RRV and OPV)	Mike Levine
8:20–8:35	OPV and Intussusception—U.S. Studies	Phil Rhodes
8:35–8:50	OPV and Intussusception—Non-U.S. Studies	Elizabeth Miller
8:50–9:10	Overview of the IS and OPV Meeting	Neal Halsey
9:10–10:10	Round Table Discussion*: Assessing the Risk of IS After Oral Vaccines, Especially OPV Participants: Lone Simonsen, Victor Caceras, M.K. Bhan	

10:10–10:45 Break

Session 8. Assessing and Managing Risk and Benefit

Moderator: Martin Myers

10:45–11:15	Risk Assessment: An Assessment of the Risks and Benefits of RRV for U.S. Children	David Salisbury
11:15–11:45	Risk Management: Putting Risk Assessment Into Perspective	Ed Marcuse
11:45–12:15	Assessing and Managing Risk in Developing Societies	Jacob John
12:15–1:00	Round Table Discussion*: Other Perspectives on Risks and Benefits A Regulator's Perspective Prescribing Physician's Perspective The Ethics of Trading One Disease for Another Programmatic Perspectives	Norm Baylor Tom Saari Charles Weijer David Salisbury

12:30–1:30 Lunch

Session 9. The Future

Moderator: George Curlin

1:30–1:50	Pre-licensure Detection of Adverse Events: The Role of Disease Burden on Estimating Sample Size	Jesse Goodman
1:50–2:10	Moving Forward—The View From Industry	TBA
2:10–2:30	Moving Forward—The View From Industry	TBA
2:30–2:50	Other Means To Minimize the Risk	Larry Pickering
2:50–3:10	Balancing Benefit and Risk on Consent Forms	Charles Weijer
3:10–3:30	Future of Rotavirus Vaccines: EPI Perspective	Octavio Oliva
3:30–3:45	Wrap-up	Georges Peter

4 p.m. Adjourn